# Purified fatty acids for endometriosis clinical trial

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>			
01/05/2017		[X] Protocol			
Registration date	Overall study status Completed	Statistical analysis plan			
30/05/2017		[X] Results			
<b>Last Edited</b> 14/06/2023	Condition category Urological and Genital Diseases	Individual participant data			

# Plain English summary of protocol

Background and study aims

Endometriosis is a common condition where tissue that behaves like the lining of the womb (endometrium) is found in other parts of the body. It affects 6-10% of women and causes severe pelvic pain. Endometriosis can be treated surgically or medically. However, symptoms often come back after surgery and the currently available medical treatments are hormones which have undesirable side effects and are contraceptive. Omega-3 purified fatty acid (PUFA) supplements may reduce endometriosis-associated pain, have minimal side effects and no effects on fertility. The aim of this small study is to assess the feasibility of conducting a larger study of PUFA for endometriosis-associated pain.

Who can participate? Patients aged 18-50 with endometriosis

What does the study involve?

Participants are randomly allocated to receive soft gelatin capsules containing either omega-3 purified fatty acids (fish oil) or olive oil, and are advised to take two capsules per day, one in the morning and one in the evening for 8 weeks. Pain is measured at the start and end of the study and blood samples are collected to measure fatty acid levels.

What are the possible benefits and risks of participating? PUFAs are a dietary supplement and may reduce endometriosis-associated pain. They have minimal side effects and no effects on fertility.

Where is the study run from? Royal Infirmary of Edinburgh (UK)

When is the study starting and how long is it expected to run for? October 2013 to May 2017

Who is funding the study? University of Edinburgh (UK) Who is the main contact?

1. Mrs Ann Doust (public)
ann.doust@ed.ac.uk

2. Prof. Andrew Horne (scientific)

# **Contact information**

# Type(s)

**Public** 

#### Contact name

Mrs Ann Doust

#### Contact details

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## Type(s)

Scientific

#### Contact name

Prof Andrew Horne

#### Contact details

QMRI 47 Little France Crescent Edinburgh United Kingdom EH16 4TJ

# Additional identifiers

Clinical Trials Information System (CTIS)

2013-004938-15

#### Protocol serial number

Version 4

# Study information

#### Scientific Title

PurFECT: PURified Fatty acids for Endometriosis Clinical Trial: a randomised controlled trial

#### Acronym

**PurFECT** 

## **Study objectives**

Endometriosis (womb lining outside the womb) affects 6-10% of women and is associated with debilitating chronic pelvic pain. It costs the UK >£2.8 billion per year in loss of productivity. Endometriosis is managed surgically or medically. However, ~75% symptoms recur after surgery and available medical treatments ('anti-hormones') have undesirable side effects and are contraceptive. Omega-3 purified fatty acids (PUFA) have been shown in animal models to reduce factors that are thought to lead to endometriosis-associated pain, have minimal side effects and no effects on fertility. The trialists plan to perform a feasibility study to inform planning of a future multicentre trial to evaluate the efficacy of PUFA in the management of endometriosis-associated pain.

# Ethics approval required

Old ethics approval format

## Ethics approval(s)

South East Scotland Research Ethics Committee 01, 02/02/2016, ref: 16/SS/0010

# Study design

Randomised controlled double-blind feasibility study

## Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Endometriosis-related pain

#### **Interventions**

Participants are randomised to receive either omega-3 purified fatty acids (fish oil) or olive oil soft gelatin (placebo) capsules, with a dose of 1000 mg each, and advised to take two capsules per day, one in the morning and one in the evening for 8 weeks. The outcomes are measured at baseline and at the end of the study (i.e., 8 weeks).

# Intervention Type

Supplement

# Primary outcome(s)

- 1. The proportion of screened women who are eligible for the trial
- 2. The proportion of eligible patients randomised into the study
- 3. The proportion of randomised patients who take the supplement and complete questionnaires at final follow up

The outcomes will be measured at baseline and at the end of the study (i.e., 8 weeks).

# Key secondary outcome(s))

The remaining outcomes will be used to refine the research methodology of a future large RCT:

- 1. Pain, measured using the Numerical Rating Score (NRS) collected via text message during the screening phase (-1 to -4 weeks) and last 4 weeks (weeks 5-8) of the treatment phase
- 2. Eicosapentaenoic acid, arachidonic acid and docosahexaenoic acid concentrations measured from peripheral venous blood samples at baseline and 8 weeks
- 3. Quality of life, measured using SF-12 at baseline and 8 weeks
- 4. Pain, measured using the Brief Pain Inventory (BPI) at baseline and 8 weeks
- 5. Pain catastrophizing, measured using the Pain Catastrophising Questionnaire (PCQ) at baseline and 8 weeks
- 5. Pain, measures using the PainDETECT™ questionnaire at baseline and 8 weeks
- 6. Sexual activity, measured using the Sexual Activity Questionnaire (SAQ) at baseline and 8 weeks
- 7. Fatigue, measured using the Brief Fatigue Inventory (BFI) at baseline and 8 weeks
- 8. General health, measures using the General Health Questionnaire -12 (GHQ-12) at baseline and 8 weeks
- 9. Work and productivity activity impairment, measured using the Work and Productivity Activity Impairment Questionnaire- Specific Health Problem version 2.0 (WPAI-SHP) at baseline and 8 weeks
- 10. Acceptability of proposed methods of recruitment, randomisation, treatments and questionnaires, measured using a questionnaire at 8 weeks

## Completion date

01/03/2018

# Eligibility

#### Key inclusion criteria

- 1. Aged 18-50 years
- 2. Known endometriosis diagnosed from previous laparoscopy
- 3. Pain of at least 3 months duration located in the true pelvis
- 4. Worst pain score ≥4 over 4 weeks as measured by Numerical Rating Score (NRS)
- 5. Ability to provide informed consent

# Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

50 years

#### Sex

#### Female

#### Total final enrolment

33

# Key exclusion criteria

- 1. Unable to take/allergic to fish/PUFA/peanuts/soyabean
- 2. Insulin dependent diabetes
- 3. Pregnant
- 4. Taking contraindicated medications (anticoagulants)
- 5. Breastfeeding

#### Date of first enrolment

30/06/2016

#### Date of final enrolment

31/12/2017

# Locations

# Countries of recruitment

**United Kingdom** 

Scotland

# Study participating centre Royal Infirmary of Edinburgh

51 Little France Crescent Edinburgh United Kingdom EH16 4SA

# Sponsor information

# Organisation

University of Edinburgh and NHS Lothian

#### **ROR**

https://ror.org/03q82t418

# Funder(s)

# Funder type

#### Funder Name

University Of Edinburgh

# Alternative Name(s)

Universitas Academica Edinburgensis, Oilthigh Dhùn Èideann, The University of Edinburgh, University of Edinburgh in United Kingdom, Edin, Tounis College, King James' College, Athens of the North, ED, Edin

#### **Funding Body Type**

Government organisation

# Funding Body Subtype

Universities (academic only)

#### Location

United Kingdom

# **Results and Publications**

# Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

# IPD sharing plan summary

Data sharing statement to be made available at a later date

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/01/2020	20/01/2020	Yes	No
<u>Protocol article</u>	protocol	01/12/2018		Yes	No
HRA research summary			28/06/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	25/01/2016	14/06/2023	No	No